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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/915,514 | 07/27/2001 | Philippe Peltie | 034299-337 | 7058 |

7590 06/17/2003

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EXAMINER

LAVARIAS, ARNEL C

ART UNIT PAPER NUMBER

2872

DATE MAILED: 06/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

| | | | |
|-----------------|-------------------|--------------|---------------|
| Application No. | 09/915,514 | Applicant(s) | PELTIE ET AL. |
| Examiner | Arnel C. Lavarias | Art Unit | 2872 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 03 April 2003.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

4) Claim(s) 1-15 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-15 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). _____.
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. 6) Other:

DETAILED ACTION

Oath/Declaration

1. The Examiner notes that the oath or declaration is defective. See Section 1 of Paper No. 10, dated 10/7/02.

Response to Amendment

2. The amendments to the specification and abstract of the disclosure in Paper No. 11, dated 4/3/03, is acknowledged and accepted. In view of these amendments, the objections to the abstract and specification in Sections 2-3 of Paper No. 10, dated 10/7/02, are respectfully withdrawn.
3. The amendments to Claims 1-11, 13-14 in Paper No. 11, dated 4/3/03, is acknowledged and accepted. In view of these amendments, the claim objections in Section 4-5 of Paper No. 10, dated 10/7/02, are respectfully withdrawn.

Response to Arguments

4. The Applicants argue that Hoyt (US2001/0046050) and Hoyt (US2001/0033374) in view of Kopf-Sill et al. fails to teach or reasonably suggest the first means having a structure of N parallel microchannels, N being an integer, the second means having at least one coupling device for guiding the polarized light into the N parallel microchannels so as to obtain N fluorescent sections, as recited in newly amended Claim 1. The Examiner respectfully disagrees. Hoyt-Sill specifically discloses the first means for

containing constituents having N parallel microchannels (See Figures 1 and 13, specifically 622 in Figure 13). Hoyt (US2001/0046050) and Hoyt (US20010033374) already disclose light coupling means (i.e. a diffraction grating, 5 in Figure 1 of Hoyt (US 2001/0046050)) for guiding polarized light into the sample cell/microchannels such that the constituents in each sample cell/microchannel section illuminated by the light fluoresces. Although the Applicants argue limitations regarding angle of incidence of the polarized light onto the microchannels and the polarized light being guided by the microchannels, such limitations are not recited in the claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

5. Claims 1-15 are rejected as follows.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-2, 4-5, 8, 9, 11, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoyt (US2001/0046050) in view of Kopf-Sill et al.

With regard to Claims 1-2, 4, 8, and 12, Hoyt (US2001/0046050) discloses a fluorescence image device comprising first means for containing constituents to be analyzed (See for example 13 in Figure 1), second means for illuminating with polarized light the constituents to be analyzed (See for example 10 in Figure 1) and third means for reading out a fluorescence light emitted by the constituents under the action of the polarized light (See for example 18 in Figure 1), the second means having at least one coupling device, such as a diffraction grating, for guiding polarized light into the first means for containing the constituents (See for example 5 in Figure 1; paragraph 0043). Hoyt (US2001/0046050) additionally discloses the second means comprising a laser (See for example 10 in Figure 1) and the third means comprising a birefringent crystal (See for example 20 in Figures 1 or 2), such as calcite (See for example paragraphs 0045, 0049). Hoyt (US2001/0046050) lacks the first means for containing constituents to be analyzed consisting of a parallel microchannel structure. However, Kopf-Sill et al. teaches a high throughput analytical apparatus for performing fluorescence detection wherein the means for containing the constituents is a parallel microchannel plate (See Figures 1 and 13) having N parallel channels (See 622 in Figure 13), which is characterized in that the microchannels are etched in a transparent material, such as glass (See col. 7, lines 2-11). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate a parallel microchannel plate having N parallel microchannels as taught by Kopf-Sill et al. in the fluorescence imaging device as disclosed by Hoyt (US2001/0046050). One would have been motivated to do this to take

advantage of microfluidic analytical techniques, such as small sample volumes and low cost ease of fabrication of the microfluidic substrate.

With regard to Claim 5, Hoyt (US2001/0046050) discloses the invention as set forth above, except for the coupling device comprising a cylindrical lens. However, Kopf-Sill et al. teaches a high throughput analytical apparatus for performing fluorescence detection wherein the coupling device comprises a cylindrical lens (See 614 in Figure 13; col. 16, line 46-col. 17, line 25). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize a cylindrical lens as the coupling device, as taught by Kopf-Sill et al., in the fluorescence imaging device as disclosed by Hoyt (US2001/0046050). One would have been motivated to do this to provide excitation light to a longer/larger surface area of the microfluidic substrate.

With respect to Claims 9 and 11, Hoyt (US2001/0046050) discloses the invention as set forth above, except for the laser emitting substantially between 488-514 nm or 550-580 nm. However, Kopf-Sill et al. teaches a high throughput analytical apparatus for performing fluorescence detection wherein the laser is capable of emitting in a wavelength range between 330-700 nm (See col. 18, lines 19-36). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have the laser emit at substantially between 488-514 nm or 550-580 nm, as taught by Kopf-Sill et al., in the fluorescence image device as disclosed by Hoyt (US2001/0046050). One would have been motivated to do this to provide appropriate excitation wavelengths depending on the fluorescent tags selected for the sample constituents.

8. Claims 3, 13, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoyt (US2001/0046050) in view of Kopf-Sill et al. as applied to Claim 1 above, and further in view of Nordman et al.

Hoyt (US2001/0046050) in view of Kopf-Sill et al. discloses the invention as set forth above in Claim 1, except for the microchannels being flexible capillaries. However, Nordman et al. teaches a multichannel capillary electrophoresis device for use in fluorescence detection wherein the constituents flow through flexible capillaries (See for example Figures 1 or 2; col. 3, line 62-col. 4, line 57). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate flexible capillaries, as taught by Nordman et al., in the fluorescence image device as disclosed by Hoyt (US2001/0046050) view of Kopf-Sill et al. One would have been motivated to do this to provide high-pressure fluid flow for sample movement along the microfluidic substrate.

9. Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoyt (US2001/0046050) in view of Kopf-Sill et al. as applied to Claim 1 above, and further in view of Stabile et al. and Stabile et al.

Hoyt (US2001/0046050) discloses the invention as set forth above in Claim 1, except for the third means comprising a first polarizing filter and a second polarizing filter. However, Modlin et al. teaches an apparatus for performing fluorescence polarization measurements wherein the third means for reading out a fluorescence light (See for example 144 in Figure 8) comprises a first polarizing filter (See P filter of 132 in Figure 8) and a second filter (See S filter of 132 in Figure 8). Additionally, Stabile et al. teaches

an apparatus for detecting polarized fluorescence light from a sample (See for example Figures 1B or 2), wherein the first and the second polarizing filters are located on a filter wheel (See for example 4B in Figure 2; col. 10, lines 14-34). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate a first and a second polarizing filter in a filter wheel as part of the means for reading out the fluorescence light, as taught by Modlin et al. and Stabile et al., in the fluorescence image device as disclosed by Hoyt (US2001/0046050) in view of Kopf-Sill et al. One would have been motivated to do this to eliminate polarized background signals from the fluorescence signal, thus increasing the signal-to-noise ratio of the detection system, while allowing for automated selection of the polarizer.

10. Claims 10 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoyt (US2001/0046050) in view of Kopf-Sill et al. as applied to Claim 1 above, and further in view of Modlin et al.

Hoyt (US2001/0046050) in view of Kopf- Sill et al. discloses the invention as set forth above in Claim 1, except for a second microlaser for simultaneously illuminating a second area of the microchannel structure. However, Modlin et al. teaches an apparatus for performing fluorescence polarization measurements (See for example Figure 5) wherein a second laser (See 103a-d in Figure 5) simultaneously illuminates a second area of the microchannel structure (See area near 120 in Figure 5). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize a second laser to illuminate a second area of the microchannel, as taught by Modlin et al., in the fluorescence image device as disclosed by Hoyt (US2001/0046050)

in view of Kopf-Sill et al. One would have been motivated to do this to perform simultaneous top and bottom illumination with simultaneous top and bottom detection of fluorescence signals.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

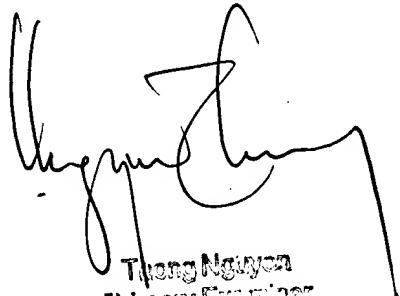
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arnel C. Lavarias whose telephone number is 703-305-4007. The examiner can normally be reached on M-F 8:30 AM - 5 PM EST.

Art Unit: 2872

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-7722 for regular communications and 703-308-7722 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1782.


Arnel C. Lavarias
June 12, 2003


Thang Nguyen
Primary Examiner